Exhibit B

Report for Gynecare TVT-O

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I. Background

a. Education and Training

I am a full-time practicing urologist in Lee County, Florida. I graduated with honors from the University of Pennsylvania in Philadelphia, Pennsylvania in 1986 with a Bachelor of Arts in Biology. My Doctor of Medicine degree was earned from Washington University, Saint Louis, Missouri in 1990. Subsequently, I completed a six year residency in Urology at the University of Rochester, Rochester, New York. My final year of urology training included serving as the Chief Resident in Urology.

Board certification was completed in 1999 after a single attempt. Board recertification was completed in 2007. Board certification in urology requires completing a certified urology residency program, the recommendation of the head of that urology program, and passage of oral and written exams. Subsequently, maintaining standards of certification is required. I am a Diplomate of the National Board of Medical Examiners, and a current member of the American Urological Association, the Southeastern Section of the American Urological Association, and the Lee County Medical Society. I have surgery privileges in the Lee Memorial Health System and Gladiolus Surgery Center in Fort Myers, Florida. I previously served on the Credentialing Committee and Medical Executive

Committee of the above health system. My curriculum vitae is attached to this report.

b. Clinical Experience with SUI Treatments

Prior to, during, and after my residency training, I was trained on many different techniques for treating stress urinary incontinence. These include retropubic colposuspension, laparoscopic urethropexy, needle suspensions, pubovaginal slings, mid-urethral slings, bulking agent injections, and artificial urinary sphincter. Soon after completing my residency, I was trained and began performing mid-urethral slings that utilized synthetic mesh. Prior to this, I was performing pubovaginal slings utilizing allograft, xenograft, and cadaveric tissue.

After completing my residency, I mostly performed non-mesh sling procedures and retropubic colposuspensions (Burch procedures). However, I have utilized all methods listed above since I began treating SUI.

Over the last decade, the vast majority of continence procedures performed in the United States have included the mid-urethral sling using synthetic mesh. These include the retropubic TVT, transobturator TVT-O, transobturator slings using the out-to-in method, the TVT-Abbrevo, and mini-slings including the TVT-Secur. I have performed over 600 of these procedures, several hundred of which were TVT-O procedures.

I have served as a preceptor for American Medical Systems, training other surgeons on the use of the Monarc Subfascial Hammock mid-urethral sling. I have also served as a Preceptor and Consultant for Ethicon/Gynecare for the TVT-O and TVT-S

devices, training both urologists and gynecologists on the use of both devices.

Compensation for my work in this case is $500 per hour. I have never previously provided expert testimony. A copy of my curriculum vitae is attached to this report, along with a list of materials I have reviewed in connection with forming the opinions included in this report, some of which may be used as exhibits at trial. The opinions set forth in this report are based on my education, training, and experience, as well as the literature and materials cited in this report and included on the attached list of materials reviewed. I hold all of the opinions set forth in this report to a reasonable degree of scientific and medical certainty. If I receive additional materials prior to the time of trial, I reserve the right to supplement this report.

II. Urinary Incontinence

a. Types, Definitions, Risk Factors, and Diagnosis

Urinary incontinence is defined as involuntary urine loss. Particular types of incontinence include stress incontinence (urine leakage due to coughing, laughing, sneezing, exercise, etc.), urge incontinence (urine leakage accompanied by urgency), and overflow incontinence (urine leakage resulting from bladder failure.) Mixed incontinence is typically a combination of SUI and urgency incontinence. Diagnosis of the above conditions is made from a combination of patient history, physical examination, and ruling out other treatable medical conditions that cause involuntary urine loss. Additional assessments can be utilized to make and clarify this condition, such as a voiding diary, urodynamic evaluation, and pad weight testing.

Urinary incontinence has been documented to affect up to 50% of women in their lifetime. SUI affects approximately 15% of women, which equates to tens of millions of American women. The cost of addressing this problem has escalated to over $1 billion per year.

Risks factors for incontinence are typically multifactorial. Obesity, smoking, vaginal deliveries, prior pelvic surgery or radiation, chronic coughing, and hereditary factors commonly contribute to involuntary urine loss. Certain medications can contribute or cause all types of incontinence. Additional but less common factors include neurologic conditions such as stroke, multiple sclerosis, Parkinson's disease, spinal cord injury, and excessive fluid intake.

b. Impact on Quality of Life

All forms of incontinence can have devastating impact on women's quality of life. Daily activity adjustments range from changing undergarments throughout the day to making extra trips to purchase incontinence pads to discontinuing exercise and avoiding social events to becoming homebound. I have had the opportunity to see patients who experience all of the above, as well as the effects this has on spouses and family. The degree of embarrassment can be dramatic enough to make women quit their job, avoid contact with others, and become social recluses. The financial, emotional, sexual, and physical problems that can arise in these women can be horrible.

III. Treatment Options for SUI

The severity of SUI and its accompanying degree of bother occupy a spectrum. This condition requires intervention when a patient finds the degree of involuntary urine loss to be

problematic or bothersome. Treatments include both non-invasive and invasive options. Frequently, multiple modalities are employed depending on the patient's needs and goals.

a. Non-Surgical SUI Treatment Options

There are a multitude of non-invasive, non-surgical treatment options for SUI. Some options simply provide a solution to saturating oneself with urine. These include absorbent pads, adult diapers, and a chronic catheter that drains the bladder into a retrieval bag. Disposable undergarments are commonly utilized and collectively cost patients billions of dollars per year. Non-surgical treatments that attempt to improve or cure SUI are quite varied in approach and mechanism of action. These include behavioral modification, pelvic muscle floor exercises, biofeedback therapy, electrical stimulation therapy, vaginal weights, and occlusive devices such as pessaries, tampons, or intravaginal bladder neck elevation implants. A motivated patient will typically demonstrate improvement with the above treatments, but rarely cure and longstanding sustained improvement. There are no FDA approved medications for the treatment of SUI. Several medications have been used in an off-label setting. However, no studies have shown any significant degree of effectiveness.

b. Surgical SUI Treatment Options

Treatment for SUI has evolved over the last several decades. Retropubic colposuspension, anterior colporrhaphy, and retropubic urethropexy used to be performed commonly, but not currently. Due to decreased invasiveness and improved efficacy, most continence surgeons have migrated to various

types of vaginal sling surgery over the last 10 years.[1] Sling types include mesh and non-mesh procedures; pubovaginal and mid-urethral variations; retropubic, obturator, and mini-sling categories. Transurethral or periurethral bulking material injection and artificial urinary sphincter are treatment options for use in specific clinical situations. Bulking material injection is less effective and may need to be repeated multiple times. The artificial urinary sphincter requires a very invasive, complex procedure typically performed at specialty centers. The lower effectiveness of these procedures makes them poor initial treatment options.

All continence surgeries have similar risks including: bleeding, infection, persistent or recurrent SUI, voiding dysfunction including overactive bladder symptoms and urinary retention, chronic pain, dyspareunia, injury to the vagina/urethra/bladder/ureters/pelvic blood vessels/pelvic nerves/bowel/pubic bone, and wound healing complications. Synthetic mesh erosion is unique to mesh-inclusive procedures, although non-absorbable sutures used in non-sling procedures can also erode through surrounding tissues. All of the above procedures include the potential need for reoperation to address certain complications.

Retropubic urethropexy, also known as needle suspension, was a previously common procedure which is now rarely, if at all, performed. This surgical technique involved small lower abdominal incisions through which a stiff metal guide was passed through the pubocervical fascia, just lateral to the

[1] Chughtai BI, et al., Midurethral Sling Is the Dominant Procedure for Female Stress Urinary Incontinence: Analysis of Case Logs From Certifying American Urologists. Urology 2013 Dec;82(6):1267-71; Clemons JL, et al., Impact of the 2011 FDA Transvaginal Mesh Safety Update on AUGS Members' Use of Synthetic Mesh and Biologic Grafts in Pelvic Reconstructive Surgery. Female Pelvic Med Reconstr Surg 2013;19:191-98; IUGA Stress Urinary Incontinence – A Guide for Women (2011).

proximal urethra on both the right and left side. This was followed by anchoring nonabsorbable suture to the pubocervical fascia with or without inclusion of the vaginal wall. The other end of the suture was passed back through the abdominal incision, followed by lifting of the anterior vagina which included both the proximal urethra and bladder neck after the abdominal suture was tied. This outpatient procedure commonly resulted in extended postoperative pain due to pressure placed on the lower abdominal fascia and muscle. As more surgeons became trained in more effective and durable vaginal sling procedures, the retropubic urethropexy was abandoned.

Retropubic colposuspension—more specifically, the Burch procedure—is an effective surgical treatment for SUI. This procedure requires a sizeable abdominal incision and entry into the abdominal cavity. The anterior vaginal wall is elevated with suture placed through pubocervical fascia, then anchored to Cooper's ligament, a structure adherent to the bony pelvis. This procedure adds little additional morbidity and recovery when performed concurrently with necessary extirpative surgery of the uterus, ovaries, fallopian tubes, and cervix. However, as a sole procedure, the retropubic colposuspension carries a longer operative time, a longer hospital stay, increased postoperative pain, longer convalescence, and typical return to work and strenuous activity in 4-6 weeks. The Burch procedure can also be performed laparoscopically, resulting in a shorter hospital stay and more prompt return to normal daily activity. This procedure is technically more difficult and highly variable regarding how it is performed. Studies have demonstrated that the success rates in providing continence are at best, similar to—with some studies demonstrating inferior results when compared to—newer and less invasive techniques such as mid-urethral slings. Some

long-term studies have shown success rates with the Burch procedure to drop significantly after ten years. For example, the Kjolhede 14-year study showed a decline in cure rates with only 19% of patients reporting that they were completely continent.[2] The Alcalay long-term study of the Burch colposuspension showed declining cure rates for 10-12 years, at which point a plateau of 69% was reached.[3]

The risks of retropubic or laparoscopic colposuspension are listed above. Additional risks of all surgeries that require entrance into the abdominal cavity or retropubic space include injury to any intra-abdominal or retropubic structures, ileus, incisional hernia, and future bowel obstruction due to adhesions. As compared to sling procedures, Burch procedures have higher rates of wound infection, bowel injury, and vaginal and bladder perforation. For patients considering the Burch procedure versus pubovaginal sling—described below—the latter is recommended to maximize cure of SUI.[4]

Bladder neck fascial slings, also known as pubovaginal slings, have been performed for decades. These procedures became more popular in the early 1990s as surgeons wanted less invasive and more effective alternatives. The patient undergoing a pubovaginal sling typically had an outpatient procedure or an overnight hospital stay. However, the vaginal aspect of the surgical dissection was extensive and accompanying blood loss could be significant. The patient also typically required a small abdominal incision and suprapubic catheter which added to morbidity. The surgical technique to

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[2] Kjolhede P, Long-term efficacy of Burch colposuspension: a 14-year follow-up study. Acta Obstet Gynecol Scand 2005;84:767-72.
[3] Alcalay M, et al., Burch colposuspension: a 10-20 year follow-up. Br J Obstet & Gynaecol, 1995 Sep;102(9):740-45.
[4] Schimpf MO, et al., Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol 2014;211:71.e1–27.

perform these procedures is highly varied with no simple, easily reproducible technique available. In addition, the various sling materials included: synthetics, autologous, allograft, xenograft, and in-situ tissue. The quality and biocompatibility of these different slings made reproducibility difficult. Safety, durability, and outcomes data were lacking. Early-used synthetic materials like Gore-Tex and Dacron turned out to have an excessive complication rate including fistulalization and erosion. Allograft, cadaveric, and xenograft materials were highly inconsistent in quality, with the last two choices also introducing the possibility of infection and patient refusal based on religious or personal reasons. They also present the possibility—albeit remote—of disease transmission despite sterilization efforts.

These earlier sling types have the same potential complications of mid-urethral slings, with the addition of a more prolonged recovery along with requiring several weeks before returning to work. Post-operative voiding dysfunction, including urinary retention, irritative and/or obstructive voiding symptoms was common.

On occasion, I still utilize the pubovaginal sling in certain circumstances. These include cases of severe intrinsic sphincter deficiency with a failed prior procedure; stress incontinence with a rigid and fixed urethra; and failed prior procedures that resulted in bladder or urethral injury. I always provide the patient with multiple options for stress urinary incontinence surgery, including mid-urethral sling with mesh, pubovaginal sling with non-mesh alternatives, and bulking material injection. After discussion of all risks and benefits, patients almost always prefer the less-invasive, more effective option that provides the quickest return to work and full range of activities: the mid-urethral mesh sling.

IV. Ethicon's TVT and TVT-O Mid-Urethral Slings

a. Historical Use of Polypropylene

Polypropylene mesh has been utilized by surgeons for more than 50 years. Polypropylene suture continues to be one of the most commonly used types of non-absorbable suturing material today. The most popular use has always been for hernia repair surgery. Hernia recurrence has decreased dramatically since incorporation of polypropylene mesh. The mesh has been used for decades as an integral part of various urologic and gynecologic procedures. Many biotech companies continue to provide polypropylene mesh in various sizes and surgical procedure kits to assist surgeons in providing their patients the best outcomes possible.

b. Development of Tension-Free Vaginal Tape (TVT) Using Prolene Mesh

In the mid-1990s Dr. Ulf Ulmsten, a Swedish surgeon, developed an innovative surgical technique for the treatment of female stress urinary incontinence after many years of research. The technique involved placing a sling at the midurethra rather than at the bladder neck. The technique was performed vaginally, involved very small incisions, and could be performed under local anesthesia in about thirty minutes as an outpatient procedure. The procedure was based on what Dr. Ulmsten and Dr. Petros called the "Integral Theory," which posited that both stress and urge incontinence symptoms may derive from laxity in the vagina "caused by defects within the vaginal wall itself, or its supporting structure i.e. ligaments, muscles, and their connective tissue

insertions."[5] The procedure was designed to compensate for that laxity by correcting the "inadequate urethral support from the pubourethral-vesical ligaments and the suburethral vaginal wall. Ulmsten and colleagues experimented with a variety of sling materials, including Gore-Tex and Mersilene, but found that those materials had an approximately 8–10% rejection rate. The surgeons ended up selecting lightweight, large-pore, monofilament, knitted Prolene mesh as the most suitable mesh material to use for the sling after finding that there were no rejections or healing defects with the Prolene slings. The surgeons found that "[t]he small incisions and canals involved with this technique minimized the surgical trauma and enabled the operation to be performed under local anesthesia."[6] One of Ethicon's medical directors met with Dr. Ulmsten in 1995 to learn more about the procedure, and Ethicon ultimately purchased the rights to the sling device, which became known as the TVT device.

Ethicon's TVT device consists of a strip of lightweight, Type I,[7] monofilament, knitted Prolene mesh 1.1 cm wide and 45 cm long attached to two reusable stainless steel trocars used for implanting the mesh. The mesh is covered with sheaths that are removed once the mesh is placed. Implantation of the TVT device involves making a small incision under the midurethra and two small suprapubic incisions on the abdomen. The trocars with the mesh attached are passed through the

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[5] Petros P and Ulmsten U, An Integral Theory of Female Urinary Incontinence – Experimental and clinical considerations. Acta Obstet Gynecol Scand 1990;69 Suppl 153:7-31.

[6] Ulmsten U, et al., An ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence. Int Urogynecol J 1996;7:81–86.

[7] "Type I" meshes are totally macroporous meshes containing pores larger than 75 microns, "which is the required pore size for admission of macrophages, fibroblasts (fibroplasia), blood vessels (angiogenesis) and collagen fibers into the pores…." Amid PK, Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia 1997;1:15–21.

suburethral incision, passing the mesh through the retropubic space and exiting through the suprapubic abdominal incisions. Once the mesh is properly placed—in a tension-free manner—the trocars and sheathes are removed, the suburethral incision is closed, along with the suprapubic incisions.

The TVT device became very popular, very quickly for several key reasons. This new procedure provided a less invasive option than all other currently employed alternatives. Easy reproducibility of the procedure and a quick physician learning curve made the TVT attractive to most surgeons who performed continence surgery. The low cost self-contained kit required minimal additional instrumentation, and minimal surgeon assistance allowed the procedure to be promptly adopted at all varieties of surgical facilities. Various types of anesthesia were utilized depending on the requirements and desires of the patient, surgeon, and anesthesiologist. This typically outpatient procedure requiring less than 30 minutes of operating room time benefited patients. Patients usually were discharged without indwelling catheters, and wound closure techniques required no specific post-operative office visit. Also, procedure efficacy was immediately available to patient and surgeon.

Studies demonstrating the effectiveness of TVT procedures have been published in urology and gynecology journals throughout the world. There are currently more than 100 randomly controlled trials that have been produced at a multitude of academic medical centers, making this product the most commonly studied continence procedure in history. Many published reviews have indicated the overall effectiveness and acceptable side-effect profile of this mesh

product.[8] The quality of these studies have been aggressively dissected and critiqued by academic physicians worldwide revealing the identification of high quality study design and investigation. Currently, TVT procedures have widespread acceptance and has been identified by most continence surgeons as the current "gold standard."

As a urologic surgeon, I have been performing sling procedures my entire professional career. Initially I performed

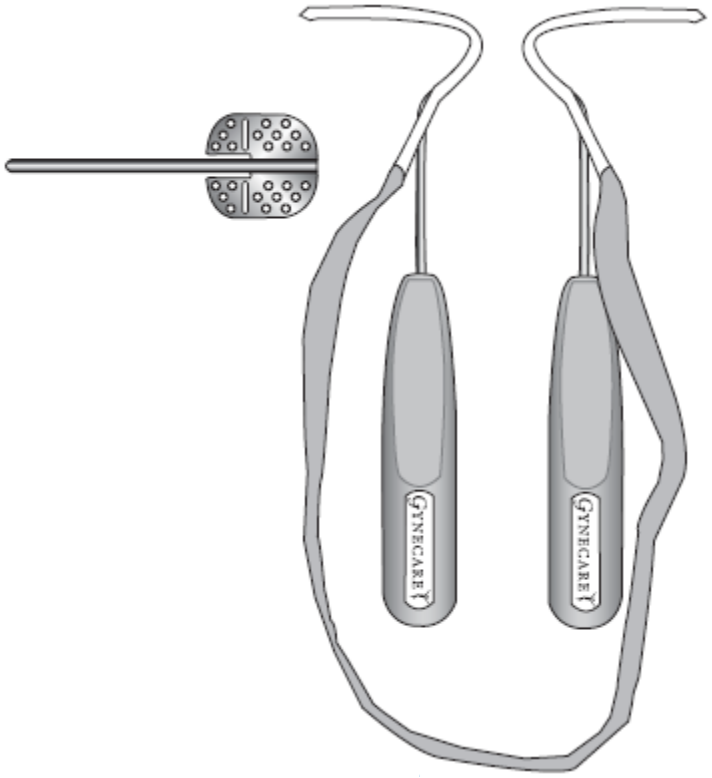
[8] Nilsson CJ, Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J, 2013 Aug;24(8):1265–9; Olsson I, et al., Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence. Int Urogynecol J 2010;21:679-683; Serati M, et al., Tension-free Vaginal Tape for the Treatment of Urodynamic Stress Incontinence: Efficacy and Adverse Effects at 10-Year Follow-Up. Eur Urol 2012;61:939-946; Heinonen P, et al., Tension-free vaginal tape procedure without preoperative urodynamic examination: long-term outcome. Int J Urol 2012 Nov;19(11):1003-9; Laurikainen E, et al., Five-year results of a randomized trial comparing retropubic and transobturator midurethral slings for stress incontinence. Eur Urol. 2014 Jun;65(6):1109-14; Aigmueller T, et al., Ten-year follow-up after the tension-free vaginal tape procedure. Am J Obstet Gynecol 2011 Nov;205(5):496.e1-5; Svenningsen R, et al., Long-term follow-up of the retropubic tension-free vaginal tape procedure. Int Urogynecol J 2013 Aug;24(8):1271-8; Wu J, Surgical therapies of female stress urinary incontinence: experience in 228 cases. Int Urogynecol J 2010;21:645-649; Hil Song P, The 7-year outcome of the tension-free vaginal tape procedure for treating female stress urinary incontinence. 2009 BJU Int, 104, 1113-1117; Christian J, et al., Long-term outcomes of TVT and IVS operations for treatment of female stress urinary incontinence: monofilament vs. multifilament polypropylene tape. Int Urogynecol J 2009;20:703-709; Kuuva N, et al., Long-term results of the tension-free vaginal tape operation in an unselected group of 129 stress incontinent women. Acta Obstetrica et Gynecologica 2006;85:482-487; Bjelic-Radisic V, Patient related outcomes and Urinary Continence Five Years after the Tension-Free Vaginal Tape Operation. Neurourology and Urodynamics 2011;30:1512-1517; Liapis A, Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5 and 7 year follow-up. Int Urogynecol J 2008;19:1509-1512; Jelovsek JE, et al, Randomized trial of laparoscopic Burch colposuspension versus tension-free vaginal tape: long-term follow up. BJOG 2008;115:219-225; McCracken GR, Five Year Follow-up Comparing Tension-Free Vaginal Tape and Colposuspension. Ulster Med J 2007;76 (3) 146-149; Chene G, Long-term results of tension-free vaginal tape (TVT) for the treatment of female urinary stress incontinence. European Journal of Obstetrics and Gynecology and Reproductive Biology, 2007;134:87-94.

pubovaginal slings using cadaveric, allograft, and xenograft as supportive material. Although an effective procedure, I found the variability of biologic sling material was dramatic and many times unsatisfactory. In addition, the depth of vaginal and pelvic dissection along with problematic bleeding kept me searching for a better alternative. After the initial studies reporting the efficacy and safety of polypropylene slings became available, I began performing the retropubic TVT, soon followed by the outside-in transobturator approach, then the inside-out transobturator approach utilized with the Ethicon TVT-O device. Following the incorporation of transobturator slings into my practice, I started also using mini-slings.

Following the success of the TVT device, surgeons developed a method of implanting the TVT mesh via a transobturator approach in order to reduce the incidence of bladder injury, retention, and other complications. Delorme and colleagues developed a procedure that involved passing the mesh tape through the obturator foramina from an outside-to-inside approach.[9] The TVT-O device was developed by Dr. Jean de Leval in 2003 in an attempt to reduce the amount of urethral and bladder injuries that could result from an outside-to-inside passage. The TVT-O utilizes the same lightweight, large-pore, knitted monofilament Prolene mesh as the TVT device. The mesh in the TVT-O device is 1.1 cm wide by 45 cm long. The mesh is covered by plastic sheathes, and is attached to single-use helical passers. The device also includes an Atraumatic Winged Guide that facilitates the passage of the helical passers through the dissection tract. Rather than passing through the retropubic space and exiting through suprapubic incisions, the

[9] De Leval J, Novel Surgical Technique for the Treatment of Female Stress Urinary Incontinence: Transobturator Vaginal Tape Inside-Out. Eur Urol 2003;44:724-30; Delorme, E, Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women. Prog Urol 2001;11(6):1306.

mesh is passed laterally through the obturator foramina, exiting through small incisions in the patients' medial thighs. By avoiding the retropubic space, the device's transobturator passage avoids potential injury to the bladder and bowel.



While continuing to use synthetic polypropylene mesh as my sling material of choice, I gravitated to the TVT-O for several reasons. I found the transobturator procedure technically easier and more reproducible to perform. The complication of bladder, urethral, major vascular structures, and bowel perforation became almost nonexistent due to a more localized technique. I was and still am a proponent of a more horizontal "hammock" sling position than the more vertical "U-type" sling position. In both my early and current experience, the "hammock" position of the TVT-O resulted in less post-operative irritative and obstructive voiding symptoms. This has also been supported by multiple high-quality randomized controlled studies. From an aesthetic viewpoint, many patients

also prefer bilateral inner thigh incisions rather than lower abdominal incisions. The TVT-O is one of my most commonly used devices to treat SUI.

c. The safety and efficacy of the TVT-O mid-urethral sling.

There is a significant body of data supporting the use of synthetic mesh mid-urethral slings in general—and the TVT-O device in particular—for the treatment of female SUI. In 2003, Dr. de Leval published the results of a trial involving 107 patients treated with what became the TVT-O device. There were no perioperative complications, injury to the urethra, bladder, nerves, or bowel, and significant (>100 ml) intra-operative bleeding did not occur. There were no cases of vaginal wall perforation. Twenty-seven (15.9%) patients complained of immediate post-operative pain in the thigh folds, but the symptoms usually abated within two days. At one month following the procedure, pain was not reported by any of the patients. Dr. de Leval concluded based on this initial short-term study that the technique was "feasible, accurate, quick, and simple, and avoids the urethra, bladder, bowel, neurological and vascular injuries."[10]

Dr. de Leval and colleagues subsequently published the results of a prospective study involving 253 patients treated with the TVT-O device with a minimum of one year of follow-up. The authors found the SUI complete cure rate was 91%, they saw no significant intraoperative complications, and no patients experienced vaginal or urethral erosion.[11] In 2008, Dr. de

[10] De Leval J, Novel Surgical Technique for the Treatment of Female Stress Urinary Incontinence: Transobturator Vaginal Tape Inside-Out. Eur Urol 2003;44:724-30;
[11] Waltregny D, et al., Inside Out Transobturator Vaginal Tape for the Treatment of Female Stress Urinary Incontinence: Interim Results of a Prospective Study After a 1-Year Minimum Follow up. J Urol 2006 Jun;175:2191–5.

Leval and colleagues published the results of a three-year study of 102 consecutive patients undergoing the TVT-O procedure. They found disappearance and improvement of SUI in 88.4% and 9.3% of the patients, respectively. They had no cases of erosion or persistent pain, but four patients required tape release or resection. The authors concluded that the TVT-O procedure was "safe and effective treatment of female SUI, with maintenance of high cure rates after a 3-yr minimum of follow-up."[12]

Several intermediate- and long-term studies of the TVT-O device have been published. In 2012, Drs. Dali Cheng and Caigang Liu published the results of their study of the use of the TVT-O device in 103 patients with a minimum follow-up period of five years. They saw a complete cure of SUI in 87.4% of patients, with improvement in approximately 92%. They found quality of life scores and incontinence severity to be largely improved following the procedure. While they also observed postoperative voiding difficulties in 17.4% requiring catheterization for various periods, the authors concluded that the TVT-O was a novel, safe, and effective device for the treatment of female SUI.[13]

In 2010, Dr. Liapis and colleagues published a four-year follow-up study involving 115 patients. They found an objective cure rate of 82.4% in patients who underwent only the TVT-O procedure, and 80.5% in patients who underwent both a TVT-O procedure and anterior colporrhaphy. Subjective cure was 81% in patients undergoing only TVT-O and 76% in patients

[12] Waltregny D, et al., TVT-O for the Treatment of Female Stress Urinary Incontinence: Results of a Prospective Study after a 3-Year Minimum Follow-Up. Eur Urol 2008;53:401–10.

[13] Cheng D and Liu C, Tension-free vaginal tape-obturator in the treatment of stress urinary incontinence: a prospective study with five-year follow-up. Eur J Obstet & Gynecol and Reprod Biol 2012;161:228–31.

who also had anterior colporrhaphy. Post-operative pain developed in 12.1% of TVT-O-only patients and 9.7% of TVT-O and anterior colporrhaphy patients, but lasted only 1-2 weeks in all but one patient, in whom it lasted for four months. The authors noted that the pain was managed effectively with NSAIDs. The authors concluded that the TVT-O had a high cure and improvement rate with a very low complication rate, and that the technique was promising while awaiting long-term results.[14]

Dr. Roberto Angioli and colleagues published the results of their RCT studying TVT versus TVT-O with five-year follow-up in 2010. They studied 72 consecutive SUI patients and found a 72.9% cure rate with the TVT-O. Five women in the TVT-O group (16.1%) had a late complication. Sixty-two percent of the TVT-O patients were satisfied or very satisfied with the results. There were no reports of chronic pelvic pain in the TVT-O cohort and only one case of dyspareunia. There were two vaginal erosions in the TVT-O cohort. The authors concluded that both surgical techniques are safe, with low complication rates.[15]

Dr. Asnat Groutz and colleagues published a long-term study of the TVT-O in 2011. They followed sixty-five consecutive and prospectively enrolled patients who underwent TVT-O implantation. Sixty-one of the 65 patients were available for follow-up at five years. The authors found 74% of the patients had their SUI cured, with an additional 8% improved, with

[14] Liapis A, et al., Efficacy of inside-out transobturator vaginal tape (TVTO) at 4 years follow up. Eur J Obstet & Gynecol and Reprod Biol 2010;148:199–201.
[15] Angioli R, et al., Tension-Free Vaginal Tape Versus Transobturator Suburethral Tape: Five-Year Follow-up Results of a Prospective, Randomised Trial. Eur Urol 2010;58:671–77.

18% considered surgical failures. They found no cases of late tape erosion or de novo OAB.[16]

In 2013, Dr. Maurizio Serati and colleagues published a study of 191 implanted with a TVT-O after a failed anti-incontinence surgical procedure. At five years of follow-up, subjective and objective cure rates were 90.3% and 90.8%, respectively. De novo OAB was reported by 24.3% of patients, and two patients (1.1%) experienced vaginal erosion 12 months after surgery, one of which required sling removal. Nineteen (9.9%) of patients experienced groin pain 24 hours after surgery, but by one month after surgery only six women (3.1%) had groin pain. After a year, two (1.0%) of women had groin pain, but by the five-year mark, no patients reported groin pain. The authors concluded that the five-year results showed that the TVT-O procedure was highly effective, with a low incidence of complications.[17]

Dr. Eija Laurikainen and colleagues published the five-year results of a RCT comparing TVT-O and TVT retropubic slings in a multicenter trial involving 267 patients—136 of whom were treated with the TVT device and 131 of whom were treated with the TVT-O device. 94.8% percent of the women were assessed at a five-year follow-up visit. 84.7% of TVT patients and 86.2% of TVT-O patients had a negative stress test, negative pad test, and no retreatment for SUI. In terms of subjective success, 84.6% of the TVT patients and 85.6% of the TVT-O patients felt that their treatment completely met their expectations. Only 3.1% of the TVT patients and 2.4% of the

[16] Groutz A, et al., Long-Term Outcome of Transobturator Tension-Free Vaginal Tape: Efficacy and Risk Factors for Surgical Failure. J Women's Health 2011;20(1):1525–28.
[17] Serati M, TVT-O for the Treatment of Pure Urodynamic Stress Incontinence: Efficacy, Adverse Effects, and Prognostic Factors at 5-Year Follow-up. Eur Urol 2013;63:872–78.

TVT-O patients experienced de novo OAB. During the study, two TVT-O patients experienced tape problems—one extrusion at one year post-op and one with retention problems. No patients "had any sign of tissue reaction, erosion, or tape protrusion at their 5-yr follow-up."[18]

In 2014, Dr. Stavros Athanasiou and colleagues published their seven-year results of a trial involving 124 consecutive women treated with TVT-O. 81.5% of the patients were objectively cured of their SUI, and 83.5% of the patients were subjectively cured. 7% of patients reported de novo urgency. No patients experienced major perioperative complications, but one patient (0.8%) had post-operative voiding difficulties requiring tape revision and one patient (0.8%) had a vaginal erosion at the urethral mid-line one year after surgery, which required excision. At the seven-year follow-up visit, no patients had an erosion. 76.3% of the patients who had urgency symptoms before the surgery experienced an improvement at the follow-up visit. There were no reports of persistent groin pain at the long-term follow-up. The authors concluded that the TVT-O procedure provided "high long-term efficacy, clinically meaningful improvement in patients' quality of life, and an excellent safety profile."[19]

High-quality evidence has shown the complication rates with mid-urethral slings such as the TVT-O to be low. A 2008 systematic review and meta-analysis summarized RCTs comparing outcomes for patients treated with the TVT device

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[18] Laurikainen E, et al., Five-year Results of a Randomized Trial Comparing Retropubic and Transobturator Midurethral Slings for Stress Incontinence. Eur Urol 2014 Jun;65(6):1109–14.

[19] Athanasiou S, et al., Seven years of objective and subjective outcomes of transobturator (TVT-O) vaginal tape: Why do tapes fail? Int Urogynecol J 2014;25:219–25.

versus the TVT-O device and noted erosion rates between 0–3.7% with the TVT-O.[20]

A 2010 Cochrane Review noted lower objective cure rates for transobturator procedures than retropubic procedures, but no difference in subjective cure rates. It also found that transobturator procedures were associated with less voiding dysfunction, blood loss, bladder perforation, and operative time than retropubic slings. The authors also observed that monofilament tapes such as those used with the TVT-O and TVT "had significantly higher objective cure rates (RR1.15, 95% CI: 1.02-1.30) compared to multifilament tapes and fewer tape erosions (1.3% vs. 6% RR 0.25, 95% CI: 0.06-1.00)." They found that "[m]inimally invasive synthetic suburethral sling operations appeared to be as effective as traditional suburethral slings . . . but with shorter operating time and less postoperative voiding dysfunction and de novo urgency symptoms." They also found that "[m]inimally invasive synthetic suburethral sling operations appeared to be as effective as open retropubic colposuspension (subjective cur rate at 12 months . . . with fewer perioperative complications, less postoperative voiding dysfunction, shorter operative time, and hospital stay but significantly more bladder perforations."[21]

A 2015 Cochrane review analyzed 81 separate studies involving 12,113 women. Fifty-five of the trials involving

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[20] Novara G, et al., Complication Rates of Tension-Free Midurethral Slings in the Treatment of Female Stress Urinary Incontinence: A Systematic Review and Meta-Analysis of Randomized Controlled Trials Comparing Tension-Free Midurethral Tapes to Other Surgical Procedures and Different Devices. Eur Urol 2008;53:288–309.

[21] Ogah J, et al., Minimally Invasive Synthetic Suburethral Sling Operations for Stress Urinary Incontinence in Women: A Short Version Cochrane Review. Neurourol and Urodyn 2011 Mar;30(3):284–91.

8,652 women compared the use of the transobturator route and retropubic route. The authors found that retropubic mid-urethral sling procedures had higher morbidity than trans-obturator mid-urethral sling procedures, "though the overall rate of adverse events remained low. . . . Major vascular/visceral injury, mean operating time, operative blood loss and length of hospital stay were lower" with trans-obturator procedures. The rate of post-operative voiding dysfunction was lower with trans-obturator procedures, but groin pain was higher in that group, but suprapubic pain was lower, although both were of short duration. The overall rate of erosion in the trans-obturator group was 2.4%. In all of the studies comparing retropubic and trans-obturator slings, "there was significant improvement in sexual function from baseline scores during the follow-up period that spanned six to 24 months. . . . At 24-month follow-up, rates of superficial and deep dyspareunia were low, with no difference between the groups." The authors' analysis led them to conclude:

> "Mid-urethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence (SUI) in women and have a good safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long term. This review illustrates their positive impact on improving the quality of life of women with SUI."[22]

The Society of Gynecologic Surgeons Systematic Review Group published in 2014 a systematic review and meta-analysis of

[22] Ford AA, et al., Mid-urethral sling operations for stress urinary incontinence in women. Cochrane Database of Systematic Reviews 2015, Issue 7. Art. No.: CD006375. DOI: 10.1002/14651858.CD006375.pub3.

RCTs with at least 12 months of follow-up comparing a sling procedure to either another sling procedure or to the Burch procedure. When comparing mid-urethral slings (MUS) to the Burch procedure, they noted that the procedures have comparable rates of objective and subjective cure, and that MUS "may result in lower rates of perioperative adverse events such as blood loss, postoperative pain, operating room time, hospital stay, bowel injury, wound infection, and hematomas," whereas "Burch procedures may result in lower rates of erosion, overactive bladder symptoms, and groin pain." For women considering either a pubovaginal sling (either biologic or synthetic) or the TVT, the authors recommended the TVT for better subjective cure outcomes, and found that MUS "may result in lower rates of perioperative outcomes such as operating room time, blood loss, and hospital stay," whereas pubovaginal slings "may result in lower rates of adverse events such as urinary tract infection and vaginal perforation." The authors found that the summary estimate of incidence for dyspareunia with a trans-obturator sling was only 0.16%. Overall, the authors concluded that "the evidence supporting use of MUS and pubovaginal slings is of high quality."[23]

In 2015, Dr. Giovanni Tommaselli and colleagues published a systematic review and meta-analysis of medium- and long-term outcomes following implantation of synthetic mesh mid-urethral slings. They included data from 49 studies, and found that retropubic and trans-obturator slings had similar objective cure rates, but the latter had lower subjective cure rates. No difference was seen in the rate of persistent pain after the perioperative period in the retropubic and trans-obturator approaches. Bladder/urethral perforations were

[23] Schimpf MO, et al., Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol 2014 Jul;211(1):71.e1–71.e27.

more common following retropubic procedures, but vaginal injuries and pain were more frequent with trans-obturator procedures. Persistent or chronic pain was reported in only 30 patients out of 2,432 trans-obturator patients (1.2%). TVT-O, however, "was associated with a significantly lower incidence of vaginal injuries than [outside-in] TOT" procedures. The authors found that both retropubic and trans-obturator procedures have high objective and subjective cure rates in the long- and medium-term that are backed by a high safety profile.[24]

In 2011, the FDA systematically evaluated the peer-reviewed scientific literature to study the safety and effectiveness of mesh procedures to correct SUI. "After considering all available data on both safety and effectiveness, and considering the risk/benefit profile" of MUS, the FDA concluded "that new premarket clinical trials are not warranted for minimally invasive slings for SUI unless the device has new features (e.g. new polymer or coating) that could affect device performance."

Based on the extensive body of data supporting the safety and efficacy of synthetic mesh midurethral slings, they have replaced the Burch retropubic colposuspension and pubovaginal slings as "the new gold standard first-line surgical treatment for women with uncomplicated SUI," whether inserted via a retropubic or transobturator approach.[25]

Numerous professional organizations have issued position statements or guidelines noting surgeons' widespread use and

[24] Tommaselli GA, et al., Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis. Int Urogynecol J 2015 Sep;26(9):1253–68.
[25] Cox A, et al., Surgical management of female SUI: is there a gold standard? Nat Rev Urol 2013;10:78–89.

preference for midurethral slings. In 2014, the American Urogynecological Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) issued their Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence, which stated: "The polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women." The position statement also notes that "[a] broad evidence base including high quality scientific papers in medical journals in the US and the world supports the use of the MUS as a treatment for SUI. There are greater than 2000 publications in the scientific literature describing the MUS in the treatment of SUI. These studies include the highest level of scientific evidence in the peer reviewed scientific literature." It also states: "This procedure is probably the most important advancement in the treatment of stress urinary incontinence in the last 50 years and has the full support of our organizations which are dedicated to improving the lives of women with urinary incontinence."[26] AUGS has also issued a Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders that notes: "Full-length midurethral slings, both retropubic and transobturator, have been extensively studied, are safe and effective relative to other treatment options and remain the leading treatment option and current gold standard of care for stress incontinence surgery."

AUGS & SUFU are not alone in their praise of midurethral slings. The American Urological Association's (AUA) Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence notes that "[s]uburethral synthetic polypropylene mesh sling placement

[26] AUGS-SUFU Position Statement on Mesh Midurethral Slings for SUI, 2014 Jan.

is the most common surgery currently performed for SUI," and further states:

> "Extensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female SUI, with minimal morbidity compared with alternative surgeries. Advantages include shorter operative time/anesthetic need, reduced surgical pain, reduced hospitalization, and reduced voiding dysfunction. Mesh-related complications can occur following polypropylene sling placement, but the rate of these complications is acceptably low. Furthermore, it is important to recognize that many sling-related complications are not unique to mesh surgeries and are known to occur with non-mesh sling procedures as well. It is the AUA's opinion that any restriction of the use of synthetic polypropylene mesh suburethral slings would be a disservice to women who choose surgical correction of SUI."[27]

The 2012 American Urological Association's SUI Guidelines noted low complication rates for synthetic mid-urethral slings (1% incidence of pain, 0% incidence of sexual dysfunction).[28]

In September 2013, the National Institute for Health and Care Excellence issued its Clinical Guideline 171 titled "Urinary incontinence: The management of urinary incontinence in women." The guideline suggests that surgeons offer synthetic midurethral sling surgery, open colposuspension, or

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[27] AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence, 2011.

[28] AUA Guidelines for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update (2012), Appendix A16.

autologous rectus fascial sling if conservative management for SUI has failed. It goes on to note that surgeons should "use procedures and devices for which there is current high quality evidence of efficacy and safety" when deciding which synthetic midurethral slings to offer a patient. And it specifically lists the TVT and TVT-O slings as two of the devices for which there is currently high quality evidence of efficacy and safety.[29]

The International Continence Society published an ICS Fact Sheet in July 2013, which provides a background on urinary and fecal incontinence. That fact sheet notes that, "[w]orldwide, midurethral slings comprised of synthetic mesh have become the treatment of choice for SUI. Long-term data are robust and demonstrate durable efficacy with a very low complication rate, particularly in experienced hands."

In November 2015 the American College of Obstetricians and Gynecologists (ACOG) and AUGS issued their Practice Bulletin Number 155, providing clinical management guidelines for obstetricians-gynecologists on urinary incontinence in women. The guidelines state that "[s]ynthetic midurethral slings demonstrate efficacy that is similar to traditional suburethral fascial slings, open colposuspension, and laparoscopic colposuspension," but are associated with fewer adverse events than suburethral fascial slings and less voiding dysfunction than open colposuspension. "For these reasons, midurethral synthetic mesh slings have become the primary surgical treatment for stress urinary incontinence in women." The guidelines also note that, while "controversy exists about the role of synthetic mesh used in the vaginal repair of pelvic organ prolapse, there are substantial safety and efficacy data

[29] National Institute for Health and Care Excellence, Urinary incontinence: The management of urinary incontinence in women, Sept. 2013 at guidance.nice.org.uk/cg171.

that support the role of synthetic mesh midurethral slings as a primary surgical treatment option for stress urinary incontinence in women."

The TVT-O sling is available in a mechanically cut version and a laser-cut version. I have used mechanically cut TVT-O slings and I have used laser-cut TVT-Abbrevo and TVT-Secur slings, and I have not found there to be a clinically significant difference in the way the mesh itself performs. In my patients in whom I implanted a mechanically cut TVT-O sling, I have not seen fraying, roping, or curling as plaintiffs' experts have suggested, nor am I aware of published studies indicating the presence of such issues or any clinical significance. The strong efficacy and safety exhibited in the published literature on MUS predating the availability of laser-cut mesh slings is consistent with the strong efficacy and safety exhibited in the published literature since laser-cut mesh has been available. In my opinion, both laser-cut and mechanically cut TVT mesh is safe and effective and state of the art.

Nor have I seen any clinically significant contraction in the TVT-O mesh slings that I have used. In my experience, tissue ingrowth occurs as expected following implantation of the sling, and while that scar tissue can be expected to contract to an extent, I have not seen contraction of the tissue that leads to problems.

Some have suggested that the mesh used in the TVT-O and other TVT devices is potentially carcinogenic. The published literature refutes any such idea.[30] Prolene polypropylene

[30] King A, et al, Current Controversies Regarding Oncologic Risk Associated with Polypropylene Midurethral Slings. Curr Urol Rep 2014;15:453; Moalli P, et al., Polypropylene mesh: evidence for lack of carcinogenicity. Int Urogynecol J 2014, DOI 10.1007/s00192-014-2343-8; AUGS & SUFU, Frequently Asked Questions by

sutures have been used in millions of patients since the 1960s and I am unaware of any case reports of cancer associated with the use of those sutures. Prolene polypropylene mesh slings have been used in millions of SUI patients as well, and I am unaware of any case reports of cancer implicating polypropylene mesh as the cause.

Plaintiffs experts have offered the opinion that the mesh in the TVT family of products is cytotoxic and degrades. I disagree. Studies relied on by plaintiffs' experts such as the Clavé study or others that show SEM images of mesh fibers with surface cracking do not appear to account for pre-analysis alteration from explantation, handling, or processing. The Clavé study involved an analysis of a sample that was only 32 out of the original 100 specimens, and the authors did not explain how that particular sample was selected. The surface cracking shown in the study could be from handling or explantation of the mesh, or it could be cracked biomaterial on the outside of the mesh.[31] If the mesh used in the TVT-O degraded as opined by plaintiffs' experts, surgeons would routinely see that in their practice and the slings would not have the excellent efficacy and safety results that they have. I have not observed any clinically significant degradation of TVT-O slings in my practice, nor have I heard any reports from colleagues regarding any such degradation. Nor have I seen any cytotoxicity in the mesh. Again, if the mesh was cytotoxic, it would not be well-tolerated by the body as reported in the numerous studies referenced above.

Providers—Mid-urethral Slings for Stress Urinary Incontinence. (available at http://www.augs.org/p/bl/et/blogaid=194).

[31] Clavé A, et al., Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. Int Urogynecol J 2010;21:261–270.

Plaintiffs' experts have also offered the opinion that larger pore or lighter weight meshes would have been safer to use in the TVT-O sling. I disagree. I am not aware of any studies showing that it would be feasible to use meshes like Ultrapro, Vypro, or Gynemesh PS as a transobturator sling material. Plaintiffs' experts have suggested an article by some Turkish surgeons looking at an incontinence procedure using Vypro, Ultrapro, and Prolene light mesh indicates those materials could have been used as an alternative design for the TVT-O. But the procedure performed by the surgeons in that study is very different from the TVT-O procedure and thus the study does not demonstrate the feasibility of using those meshes as a midurethral transobturator sling. Furthermore, there were complications such as vaginal erosions, urine retention, incontinence, and de novo urgency experienced in the Vypro, Ultrapro, and Prolene light groups.[32] Other studies have shown poor tolerance of Vypro mesh when implanted in pelvic floor surgery.[33] In my opinion, the pore size and weight of the mesh used in the TVT-O is optimal, as evidenced by the extensive evidence of efficacy and safety discussed above.

d. Ethicon Product Literature—The Instructions for Use and Patient Brochures

The TVT-O device comes packaged with an Instructions for Use (IFU) document.[34] The IFU instructs the surgeon to "Please read all information carefully." It then goes on to note that the device "should be used only by physicians trained in the

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[32] Okulu E, et al., Use of three types of synthetic mesh material in sling surgery: A prospective randomized clinical trial evaluating effectiveness and complications. Scand J Urol 2013;47:217–24.

[33] Denis S, et al., Pelvic Organ Prolapse Treatment by the Vaginal Route Using a Vypro Composite Mesh: Preliminary Results About 106 Cases. ICS IUGA Abstract 620 (2004).

[34] ETH.MESH.00860239–310.

surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT Obturator device." The IFU sets forth the indications and contraindications for use of the product and provides detailed instructions for how to use the device. The IFU also provides a list of warnings and precautions, noting, among other things:

- Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the GYNECARE TVT Obturator procedure before employing the GYNECARE TVT Obturator device.
- Acceptable surgical practice should be followed for the GYNECARE TVT Obturator procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TVT Obturator procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to patient anatomy and correct passage of the device will minimize risks.
- Transient leg pain lasting 24–48 hours may occur and can usually be managed with mild analgesics.
- As with other incontinence procedures, de novo detrusor instability may occur following a sub-urethral sling procedure utilizing the GYNECARE TVT Obturator System. To minimize this risk, make sure to place the tape as described above.

The IFU also includes a list of potential Adverse Reactions noting that punctures or lacerations of blood vessels, nerves, bladder, urethral, or bowel may occur, that transitory local irritation at the wound site and a transitory foreign body response may occur, which could result in extrusion, erosion, fistula formation, or inflammation, that infection may occur, and that over-correction or over tensioning may cause temporary or permanent lower urinary tract obstruction. In

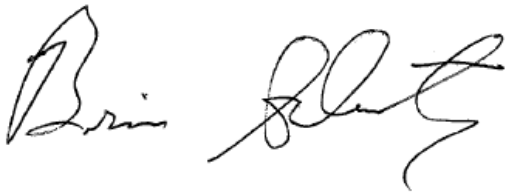
my opinion, these warnings are adequate. There is no need for Ethicon to warn surgeons about risks inherent in any pelvic floor surgery such as infection, inflammation, bleeding, scarring, bladder damage, bowel damage, nerve damage, ureteral damage, pain, pelvic pain, dyspareunia, groin pain, bladder or bowel dysfunction, fistula, anesthetic risks, wound complications such as erosion, wound dehiscence, exposure, wound herniation, hematoma, need for reoperation, failure of the operation, and anesthetic risks. Nor is there any need to warn surgeons about the severity, frequency, or permanency of any of these complications. Surgeons know from their education, training, and experience that complications can be mild, moderate, or severe, permanent or temporary, and data on complication frequency is available in peer-reviewed literature, which surgeons have an obligation to review. In my opinion, the warnings and instructions provided in the TVT-O IFU are adequate.

Ethicon also provided patient brochures to physicians to share those brochures with their patients if they saw fit. They are not a substitute for a thorough discussion between a patient and her physician regarding the treatment options and risks and benefits of those options, but they are a helpful resource for patients. The brochures provide an overview of different types of urinary incontinence, treatment options, what MUS treatment involves, suggested questions for the patient to ask the physician, expected recovery from MUS surgery, and some of the risks of MUS surgery.

e. Professional Education

My initial exposure to transobturator sling procedures began with the outside-in technique. This was soon followed by training on the inside-out technique employed by the Ethicon

TVT-O system. Training first included scientific and instructional lectures by academic leaders in the field of continence surgery. This was promptly followed by actively engaging in cadaver labs which included extensive discussion then dissection of pelvic anatomy. The TVT-O procedure was performed multiple times subsequent to which dissection of the cadaveric pelvis was performed. This unique opportunity afforded me the ability to assess and develop confidence and reproducibility of the TVT-O procedure, as well as become more skilled at identifying and treating potential surgical complications. This combination of didactic and hands-on training contributed greatly to my knowledge of the scientific basis of continence, pelvic anatomy, and pelvic surgery skills. As a regular participant in the annual Gynecare meeting for preceptors, I engaged in a host of activities furthering my knowledge of female stress urinary incontinence issues. These events included my participation in large and small group discussions, lectures by leaders in the field, and extensive presentations and discussions on complications of MUS surgery. I found the complications portion of the meeting provided me with insight on not only how to better identify and avoid complications, but how to more effectively treat them. This experience was invaluable to my continued growth as a continence surgeon.



Dated: 2/29/16

Brian Schwartz, M.D.